

REMARKS

I. Status of the claims

Claims 3-6, 8-14 and 30 are pending in this application. Applicants reserve the right to pursue any of the canceled claims in a separate application.

Claim 30 is now the only independent claim. The remaining claims have been amended to depend either directly or indirectly from claim 30. Since claim 30 has already been examined, the amendments to the claims should not raise new issues that would require a new search. Applicants therefore respectfully request that the Examiner enter these amendments.

II. Objection to the disclosure

The Examiner objected to the amendment to the disclosure filed on September 20, 2005. In particular, the Examiner stated that no support in the original application existed for deleting reference to the phrase "one or more" when referring to "one or more nonvolatile constituents."

Applicants do not agree with this objection. As explained in the Amendment filed on September 20, 2005, the original disclosure conveys that urea and the hydrophilic film-forming agent are nonvolatile constituents in the context of this invention. An amendment to refer to "nonvolatile constituents, which comprise" urea and the hydrophilic film-forming agent is therefore supported, and adds no new matter, when compared with reference to "one or more nonvolatile constituents, which comprise" urea and the hydrophilic film-forming agent. Indeed, it makes sense to delete reference to the phrase "one or more" simply because there are at least two nonvolatile constituents recited: urea and the hydrophilic film-forming agent.

The Amendment filed on December 10, 2004, made similar clarifications to the claims, and the Examiner did not raise an objection to that amendment.

In view of these remarks, applicants respectfully request that the Examiner withdraw this objection.

III. Withdrawal of novelty rejections

Applicants acknowledge that the Examiner has withdrawn the rejection of certain claims under 35 U.S.C. § 102(b) in view of GB 2 202 743. The Examiner also withdrew the rejection of certain claims under 35 U.S.C. § 102(e) in view of US 2003/0012749.

IV. Obviousness rejection in view of US 2003/0012749

A number of claims, including independent claim 30, were rejected under 35 U.S.C. § 103(a) as having been obvious in view of the disclosure of US 2003/0012749 to Kraemer et al. ("Kraemer"). This rejection did not include the subject matter of claims 9-11, which have now been amended to depend from claim 30. Applicants assume that pending claims 9-11 are already allowable over the Kraemer disclosure. If claim 11 is allowable, claim 12, which depends from claim 11, should be allowable as well.

Although applicants do not agree with the rejection of the other claims, the application has been amended to leave claim 30 as the only independent claim. Applicants respectfully traverse this rejection as it applies to claim 30, and the remaining rejected claims should be patentable for at least the same reasons by virtue of their dependency from claim 30.

Kraemer does not suggest the claimed method of hydrating brittle toenails or fingernails, comprising applying to brittle toenails or fingernails the pharmaceutical preparation recited in claim 30. Instead, Kraemer discloses preparations to be applied to pathologically altered areas, such as pathologically altered areas of fingernails and toenails, which are the result of, for example, fungal, bacterial or viral infection or psoriasis. Kraemer at ¶¶ [0012]-[0015].

The intent of the Kraemer invention is to excise the diseased portions of the toenails and fingernails. *Id.* In contrast, the method of the invention improves the health of brittle nails by hydrating them in the manner recited in claim 30. Kramer makes no mention of brittle toenails or fingernails or any hydrating effect of its compositions on brittle toenails or fingernails. For at least this reason, the pending claims would not have been obvious in view of the Kraemer application.

V. Rejection in view of U.S. Patent No. 5,874,074

The Examiner maintained the rejection of claims 1, 3-6, 8-14, 17, 19, 21, 22, 24-35, 38-42 and 44 under 35 U.S.C. §103(a) as being unpatentable over the disclosure of U.S. Patent No. 5,874,074 to Smith ("Smith"). Office Action on page 5. Applicants continue to traverse this rejection as it applies to the claims still pending.

Smith teaches the application of its compositions to skin to treat skin disorders. See Title "Occlusive/Semi-Occlusive Lotion for Treatment of a Skin Disease or Disorder;" Summary of the Invention "The present invention is an occlusive or semi-occlusive barrier moisturizing lotion useful for treating pathologies of the skin;" and therapeutic agents at col. 4, lines 47-49 "for the topical treatment of a skin disease or disorder" (underlining added). Moreover, the underlying rejection detailed on page 7 of the Office Action mentions that "[t]he composition of Smith is prepared as a lotion and applied to skin to treat pathologies of the skin (underlining added). See *also* Office Action at page 8 ("One having ordinary skill in the art would have been motivated to include an effective amount of urea with the expectation that application of the modified or optimized lotion of Smith to the skin would treat pathologies of the skin such as calluses, hard skin or corn and warts.") (underlining added).

In view of the above, the Smith disclosure does not suggest use of the presently-claimed composition, or even Smith's own lotion, to hydrate brittle fingernails or toenails as recited in claim 30.

The Examiner stated on page 6 of the Office Action that "Smith encompasses the instant method and toe and fingers have skin areas." The invention of claim 30, however, does not recite application of the solution preparation to a "toe" or "finger" generally, but rather to brittle nails of toes and fingers. The Examiner has not explained why it is believed that Smith's disclosure of using its composition on the skin area of the body to treat a skin disorder would suggest instead using the claimed composition to hydrate brittle nails.

The Examiner also stated that "it is obvious that application of the composition of Smith to the skin does not exclude application of the composition to the nails of the toes." Office Action at page 6. This statement implies that the invention is obvious unless the Smith patent explicitly states that the composition should not be applied to

brittle nails. This is not the correct application of the test for obviousness. Instead, the question here is whether the person skilled in the art would have been motivated to modify the reference teachings to carry out the claimed invention with a reasonable expectation of success. MPEP § 2141. Given that skin and nails are different, which the Examiner has not disputed, and that Smith specifically teaches that its compositions are intended for use on skin to treat skin disorders, the Examiner has not met the Office's burden of showing that the claimed invention would have been obvious.

The Office Action also stated on pages 7-8 that "it is obvious that the composition of Smith applied to the skin also gets on the nails of the toes and fingers." This appears to be speculative and, in any event, does not render the invention obvious. Smith does not disclose that its composition will inevitably contact toenails or fingernails. The lotion may not even be applied anywhere near a fingernail or toenail. See, e.g., use in the treatment of acne at col. 7, line 44, on the face of the patient, for example. Smith also discloses that the lotion can be applied by means of a fibrous or cellular sheet rather than by hand. Smith at col. 1, line 66 to col. 2, line 4. Even if the Smith lotion could contact nails, that is not determinative. The theoretical possibility of contacting a nail with the Smith composition, which is disclosed for application instead to the skin, and which is not even a composition of the invention, does not create an affirmative motivation to practice the method of claim 30.

Smith also does not teach therapeutic compositions in the form of a solution as claimed. The Examiner acknowledged that Smith discloses the preparation of an emulsion, rather than a preparation as a solution. An aqueous "solution" can only be derived from the Smith disclosure by removing the oil phase of the oil-in-water emulsion, which would require doing away with the required emollients present in the oil phase, which in turn would contradict the very teachings of the reference. Improper hindsight appears to be the only way to achieve that result.

In further explaining this rejection, the Office Action discussed the preparation of the individual phases of the emulsion as follows:

Smith prepares the [aqueous and oil] phases separately and the urea and the film-forming polymer are present in the aqueous phase as a solution and the aqueous phase is not miscible with the oil phase and the composition of Smith contains about 70% water. Smith prepares the oil

phase separately from the water phase and the urea and the PVP are soluble in water and are therefore in solution in the water phase.

Office Action at pages 6-7.

But Smith ultimately discloses that the formulation is to be applied as an emulsion to a patient since the lotion itself is an emulsion. Rather than supporting a rejection of the claims, the Examiner's comments regarding the preparation of the individual phases, which are then combined to form an emulsion, reaffirms that there is no motivation in Smith to use an aqueous solution for use in the method claimed by the applicants.

For at least the reasons discussed above, the Examiner should withdraw this rejection.

VI. Double patenting rejection

The Examiner provisionally rejected claims 17-24 and 26-29 under the judicially-created doctrine of obviousness-type double patenting in view of claims 17-24 and 26-29 of co-pending application no. 10/156,070.

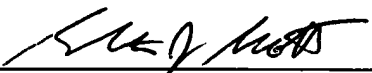
Claim 30 is the only independent claim now pending in the application, and the rejection does not apply to this claim. The cancellation of claims 17-24 and 26-29 should render this rejection moot.

In view of these amendments and remarks, applicants respectfully request reconsideration and reexamination of this application. Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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